Attorney's Docket No.: <u>705152-2001</u>

Application No.: <u>10/589,751</u>

## **AMENDMENTS TO THE CLAIMS:**

This listing of claims will replace all prior versions and listings of claims in the application:

## **LISTING OF CLAIMS:**

- 1-27. (Cancelled).
- 28. (Currently Amended) A concentrated, stable solution, comprising water and a diastereoisomeric excess of at least 75% of (6S)-sodium-folinate or (6S)-potassium-folinate.
- 29. (Currently Amended) The A solution according to claim 28, wherein the solution is sterile, prepared according to a process wherein:

amorphous (6S)-folinic acid is suspended in water, that is degassed and that is acceptable for the preparation of injection solutions or of infusion solutions, at room temperature under an inert gas atmosphere, adding in portions an aqueous solution of sodium or potassium hydroxide,

hydrogencarbonate, or carbonate until a clear solution is formed having the desired pH value, <u>and</u>

sterile-filtering the solution, and.

filling into vials or into ampoules under an inert gas atmosphere the resulting sterile solution.

30. (Previously Presented) The solution according to claim 29, wherein said amorphous (6S)-folinic acid is prepared according to a process wherein:

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an aqueous solution having a temperature from 40°C to 50°C of (6S)-calcium-folinate, and

an aqueous solution of hydrochloric acid or of acetic acid

is added to stirred water having a temperature from 2°C to 12°C simultaneously in such a way that in the obtained mixture during the addition of both of said solutions the temperature is kept at a value from 2°C to 12°C and the pH value is kept at a value from 2.5 to 3.5, and further wherein:

the formed solid is isolated by means of filtration or centrifugation, said solid is washed first with cold water and then with an aqueous organic solvent, and

said washed solid, that is amorphous (6S)-N(5)-formyl-5,6,7,8-tetrahydrofolic acid, is dried under reduced pressure.

- 31. (Previously Presented) The solution according to claim 30, wherein said stirred water, to which said two solutions are added simultaneously, has a temperature from 6°C to 10°C.
- 32. (Previously Presented) The solution according to claim 30, wherein said aqueous solution of (6S)-calcium-folinate has a concentration from 3.0 % by weight to 3.7 % by weight.
- 33. (Previously Presented) The solution according to claim 30, wherein said aqueous solution of (6S)-calcium-folinate has a temperature of 46°C.
- 34. (Previously Presented) The solution according to claim 30, wherein said aqueous solution of hydrochloric acid has room temperature and has a concentration from 10 % by weight to 20 % by weight.

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35. (Previously Presented) The solution according to claim 30, wherein for the obtained mixture during the simultaneous addition of both of said solutions the temperature is kept at a value from 6°C to 10°C.

- 36. (Previously Presented) The solution according to claim 30, wherein for the obtained mixture during the simultaneous addition of both of said solutions the pH value is kept at a value from 2.8 to 3.2.
- 37. (Previously Presented) The solution according to claim 30, wherein said obtained mixture is stirred for 1 additional hour at a temperature from 6°C to 10°C.
- 38. (Previously Presented) The solution according to claim 30, wherein said aqueous organic solvent is a 94:6 mixture (v/v) of ethanol and water.
- 39. (Previously Presented) The solution according to claim 28, containing from 2 % by weight to 15 % by weight of (6S)-sodium-folinate or (6S)-potassium-folinate.
- 40. (Previously Presented) The solution according to claim 28, wherein said solution has a pH value in the range from 7.5 to 8.5.
- 41. (Previously Presented) The solution according to claim 28, wherein said solution lacks both a stabilizer and a complexing agent.
- 42. (Currently Amended) The solution according to claim 28, wherein said solution is filled into contained in vials or into ampoules having in their interior an inert gas atmosphere.
- 43. (Previously Presented) Vials or ampoules filled with a concentrated, stable solution according to claim 28.

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44-46. (Cancelled).

47. (Previously Presented) The solution according to claim 28, wherein said solution is an injection solution or infusion solution.

- 48. (Previously Presented) The solution according to claim 30, wherein said aqueous solution of (6S)-calcium-folinate has a concentration of 3.5 % by weight.
- 49. (Previously Presented) The solution according to claim 30, wherein said aqueous solution of hydrochloric acid has room temperature and has a concentration of 18 % by weight.
- 50. (Previously Presented) The solution according to claim 28, containing from 2 % by weight to 6 % by weight-of (6S)-sodium-folinate or (6S)-potassium-folinate.
- 51. (Previously Presented) The solution according to claim 28, containing 5 % by weight of (6S)-sodium-folinate or (6S)-potassium-folinate.
- 52. (Previously Presented) The solution according to claim 28, wherein said solution has a pH value in the range from 7.9 to 8.1.
- 53. (Previously Presented) The solution according to claim 28, wherein said solution has a pH of 8.0.
- 54. (Currently Amended) The solution according to claim 28, wherein said solution is filled into contained in vials or into ampoules having in their interior a nitrogen atmosphere.
- 55. (Previously Presented) A medicament for treatment of high doses of methotrexate, formed from a solution according to claim 28.

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56. (Previously Presented) A medicament comprising a solution according to claim 28 and 5-fluorouracil.

57. (Previously Presented) A medicament for the treatment of megaloblastic anemia and dihyropteridin reductase deficiency comprising a solution according to claim 28.